

**FEDERAL SECURITY AGENCY****FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,  
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

**2451-2500****DRUGS AND DEVICES**

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

J. DONALD KINGSLEY, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *December 24, 1948.*

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**DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN  
USED ACCORDING TO DIRECTIONS**

**2451. Misbranding of Gomco ring pessary. U. S. v. 62 Devices, etc.** (F. D. C. No. 24856. Sample No. 14123-K.)

**LIBEL FILED:** June 7, 1948, Northern District of Illinois.

**ALLEGED SHIPMENT:** Between December 15, 1947, and April 1, 1948, from Buffalo, N. Y., by the Gomco Surgical Mfg. Corp.

**PRODUCT:** 62 *Gomco ring pessary devices* at Chicago, Ill., together with two circulars entitled "Technique For The Use Of The Gomco Intrauterine Silver Ring Pessary." Examination showed that the device was a metallic ring, approximately one inch in diameter, which was fashioned from a coiled spring.

**LABEL, IN PART:** "Gomco Ring Pessary."

**NATURE OF CHARGE:** Misbranding, Section 502 (j), the device was dangerous to health when used with the frequency and duration recommended and suggested in its labeling, namely, "Patient lies in the Gynecological position on the examination table. The Speculum is inserted and antiseptic wet swabs are applied to the Os in order to remove any mucous. The Tenaculum Forceps used to seize the anterior lip is held in the left hand to steady the cervix and

\*For failure to bear a label containing an accurate statement of the quantity of the contents, see Nos. 2453, 2457; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 2453, 2457; cosmetics, subject to the drug provisions of the Act, Nos. 2487-2489 (creams only), 2492.

bend it down. A Sound is introduced in order to establish the position, size and direction of the Uterine Cavity and also to determine the caliber of the cervical canal. The Speculum is then pressed posteriorly. It is most important to establish the length of the uterine cavity as the ring must be placed so as to be in contact with the upper end of the cavity. The bend in the cervical canal is straightened by pulling gently on the Tenaculum. Occasionally projecting folds in the mucous membrane of the cervical canal (especially in hypo-plastic uteri) causes some difficulty. This can be overcome by dilating the cervical canal with a Hegar's Dilator so that the introducing instrument can be passed after the dilation. This is quite easy if a No. 6 dilator can be passed. If No. 5 goes in easy it is not necessary to try No. 6 as this is wide enough for the introducing instrument. The latter is pushed in until the resistance of the fundus uteri is encountered. The ring which is compressible adapts itself to the canal while passing through it and resumes its circular shape when it gets into the uterine cavity. You can see this from an X-ray plate of the ring in situ. On withdrawing the introducing instrument, the walls of the uterus at the internal os detach the ring from the instrument and the latter comes out easily, leaving the ring behind. The Tenaculum Forceps are then removed, any blood clots are swabbed up, the Speculum is removed and a swab left on the vaginal entrance. \* \* \* Care must be taken that the lower pole of the ring is within the cavity. \* \* \* The ring may be left in for at least one year."

DISPOSITION: August 24, 1948. Default decree of condemnation and destruction.

#### DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

**2452. Misbranding of penicillin sodium. U. S. v. Joseph A. Alvarez (Proctor Laboratories). Plea of guilty. Sentence of 1 year in jail and fine of \$1,000. Sentence subsequently modified to provide for suspended sentence of 1 year, revocation of fine, and probation for 2 years. (F. D. C. No. 24251. Sample Nos. 64198-H, 64199-H.)**

INFORMATION FILED: May 27, 1948, District of New Jersey, against Joseph A. Alvarez, trading as Proctor Laboratories, at New York, N. Y.

ALLEGED SHIPMENT: On or about May 13, 1947, from the State of New Jersey into the State of New York.

LABEL, IN PART: "Penicillin Sodium Proctor \* \* \* Proctor Laboratories \* \* \* New York."

NATURE OF CHARGE: Misbranding, Section 502 (1), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or a release had been issued pursuant to Section 507; Section 502 (a), the label statements "Lot No. 77 Expiration Date Oct-1-48" and "Lot No. 90 Expiration Date Oct. 1, 1948," were false and misleading, since they represented and suggested that the article had been certified in accordance with regulations, whereas the article had not been so certified; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, in that there was no statement in the labeling of any condition, disease, or function for which the article was to be used, and in that there were no statements in the labeling of the dosage, methods, and duration of administration in accordance with which the article was to be used.

DISPOSITION: On July 26, 1948, a plea of guilty having been entered, the court sentenced the defendant to serve 1 year in jail and imposed a fine of \$1,000. On August 2, 1948, after the defendant had served seven days in jail, the court modified the sentence to provide for a suspended sentence of 1 year in jail, for the revocation of the \$1,000 fine, and for probation for 2 years.